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**The FDA's Treatment of Structure/Function Claims under the Dietary Supplement Health
and Education Act**

Karen J. Powell

Introduction

Demand in the United States for dietary supplements and herbal products has exploded in past years. One report states that demand for dietary supplements has increased almost 50 percent since 1995.¹ Congress, therefore, in response to the increased demand and other motivations (to be discussed below), has passed legislation intended to increase the amount and quality of information available to consumers in an effort to maximize the benefits of such products. Congress has attempted to develop a regulatory scheme in which an atmosphere of cooperation exists between the government, the dietary supplement industry and consumers of these products. However, it seems that Congress' intent in passing the Dietary Supplement Health and Education Act (and related legislation) has not come to fruition.

The Food and Drug Administration's Regulatory Powers

One of the missions of the FDA is to protect consumers from adulterated products (food, drugs and cosmetics) Regardless of the changes introduced since the enactment of the Federal Food, Drug and Cosmetic Act (FDCA) of 1938 and subsequent, related legislation, this mission of the FDA remains the same. The FDA is a descendent of early regulators who prosecuted charlatans who marketed questionable products, making wild claims about the medicinal qualities of potions and compounds during the nineteenth century. Pursuant

¹Linda Ciampa, *FDA Requires New Diet Supplement Labels*, <http://www.cnn.com/HEALTH/9903/23/dietary.supplements/hs~index.html>, (3/23/00).

to this mission, the Secretary of Health and Human Services has the authority to promulgate regulations to enforce federal laws, including the Federal Food, Drug and Cosmetic Act of 1938. In promulgating the enforcement regulations, the Secretary follows statutory procedures which require publication of the Secretary's proposal. Interested persons are invited to respond, and those who would be adversely effected may submit objections. If material issues are raised during this process, a hearing may be held. The powers given to the Secretary under the Federal Food Drug and Cosmetic Act have been delegated to the Commissioner of Food and Drugs. A statutory provision is available for review of orders granted for the establishment or amendment of such regulations. In reviewing promulgating regulations, courts will seek a rational basis for such regulations in consideration of pertinent circumstances and will consider whether the regulation falls within the powers delegated to the FDA.²

The FDA is recognized by Congress as having the following powers in regulating dietary supplements:

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²Drugs and Controlled Substances, 25 *Am. Jur. 2d* §90 (1996).

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History

FDA control and regulation of dietary supplements has an extensive history. The history tells a story of a tug-of-war existing between Congress and the FDA, during which the FDA has taken an aggressive stance on regulating dietary supplements and Congress ultimately has responded by severely limiting the FDA's power through legislative efforts. Methods employed by the FDA to regulate and control dietary supplements have included "classification methods, effectiveness provisions, and labeling requirements."⁴

The Pure Food and Drug Act of 1906 was an early congressional effort aimed at controlling the quality of foods and drugs which reached the public. The FDC did little in addressing the need for pre-screening of drugs, an issue later addressed in the Federal Food, Drug, and Cosmetic Act of 1938. This Act established a classification system for foods and drugs containing vitamins, which was dependent on the marketing and labeling of the products. In a nutshell, products intended to treat, mitigate or cure disease were considered drugs and those products (except for conventional foods) affecting the structure or function of the body were also considered drugs.

⁴Kelly Ann Kaczka, *From Herbal Prozac to Mark McGuire's Tonic: How the Dietary Supplement Health and Education Act Changed the Regulatory Landscape for Health Products*, 16 J. Contemp. Health L. & Pol'y 463, 478 (2000).

Labeling requirements were established in the FDCA, as well. Dietary Supplements were not addressed by the Act. However, relevant to our topic, the Act did confer power to the FDA to “regulate and declare misbranded dietary foods.”⁵ The Act gave the Secretary of Health and Human Services the authority to determine and regulate appropriate labeling requirements for foods claiming special dietary uses.⁶ It gave the FDA the power to establish the criteria for evaluating nutritional information reaching the public. The FDA, however, failed to fully answer questions regarding the labeling and regulation of some products when establishing its regulations surrounding this issue. Rather than establishing regulations to the extent of its discretionary powers, the FDA chose to regulate labeling guidelines through litigation.⁷

Litigation-based regulation of labeling claims proved inefficient, leading to FDA proposals for regulations in 1962. These regulations gave the FDA tight control over labeling claims made by manufacturers and required manufacturers to demonstrate the effectiveness of new drugs before they hit the market. As dietary supplements could be considered either drugs or food, depending on how the manufacturer marketed them. As a result, the new regulations gave the FDA authority to tightly regulate the labeling of dietary supplements.

The FDA, in general, had judicial support in its efforts to regulate dietary supplements with drug standards. As a result of the increasing market for herbs and vitamin supplements, FDA efforts to regulate the market has increased. In response, manufactures have supported legislation which narrows the FDA’s expanding regulatory efforts. The Proxmire Vitamin Mineral Amendment of 1976 expressly forbid the FDA to regulate

⁵*Id.* at 468.

⁶21 U.S.C. §403 (1998).

⁷Kaczka, *supra* note 4, at 471.

potency limits or classifying a vitamin or mineral as a drug based on its potency or to limit the marketing of multivitamins. As an initial attempt to rein in the FDA's stance on dietary supplements, the amendment had little effect on the FDA's assertive efforts to regulate supplements.

The passage of the Nutritional Labeling and Education Act of 1990 (NLEA) offered the FDA additional control over dietary supplements. It was intended to overhaul all food labeling, including the labels on dietary supplements. The Act established a nutritional labeling requirement for foods and supplements. The NLEA established that health claims made for food products were subject to the standard of "significant scientific agreement." Congress chose to establish the standard for dietary supplements on a separate section of the Act. The Act established that claims made on the labels of dietary supplements are "subject to a procedure and standard, respecting the validity of such a claim, established by regulation of the Secretary [of Health and Human Services]." ⁸

The Act opened the door to the FDA establishing procedural regulations for health claims on both food and dietary supplements. Regardless of Congress' intent in providing a separate provision for labeling regulations for supplements, the enormous discretion offered to the FDA by the ambiguous requirement allowed the FDA to implement its own interpretation of the Act's labeling requirements: "[T]he FDA took that separate requirement for supplements to mean that, if it wanted, it could apply to supplements the same 'significant scientific agreement' standard the law applied to food." ⁹ However, Congress' reaction to this move was swift.

The FDA's machinations and public pressure combined to produced additional congressional legislation: the Dietary Supplement Act of 1992 (DSA). This Act slowed FDA's efforts to implement the regulation promulgation process regarding health claims and labeling in the NLEA by placing a one-year delay on its implementation. Regardless of the powers offered to the FDA by the passage of the NLEA, the DSA

⁸21 U.S.C. § 343 (r) (5) (D)

⁹Eric F. Greenberg, *Dietary Supplements Caught in Murky Regulatory Scheme*, Chicago Daily Law Bulletin, vol. 144, no. 250 (December 23, 1998).

was an immediate effort to limit those powers. Congress ordered the FDA to review its stance on dietary supplements, but to no avail. When the one-year waiting period had passed, the FDA persisted in using the same “significant scientific agreement” standard that applied to foods.

Despite Congress’ efforts to limit the FDA’s regulatory actions, the FDA continued its assertive efforts in response to increasingly reported health-related problems attributed to the use of dietary supplements. As the FDA’s efforts were increasing, Congress responded with the passage of the Dietary Supplement Health and Education Act of 1994, which created new limits on the FDA’s efforts to regulate dietary supplements.

The Dietary Supplement Health and Education Act of 1994

Against the backdrop of the antagonistic relationship between the FDA and the dietary supplement industry, and in an effort to reduce the ambiguity and conflicts about the labeling of dietary supplements, the DSHEA amended the Federal Food, Drug and Cosmetic Act. It set forth a federal definition for “dietary supplements,” a broader meaning than the FDA employed, allowing for dietary supplements to generally be considered food.

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Congress defined “dietary supplement” to mean products that are intended to supplement the diet that contain one or more of certain dietary ingredients, such as:

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-

And, that meets other criteria specific in Section 201 (FF) (2)-(3).¹⁰

The Act also set forth a regulatory framework for dietary supplements. As noted above, the passage of the DSHEA was a response to the FDA's continued, aggressive approach to regulating dietary supplements. Congress was also motivated by the need to promote good nutrition and health through the increase of information on dietary supplements available to the public (perhaps in reaction to President Clinton's efforts for health care reform). Through the DSHEA, Congress sought to restructure the FDA's authority in regulating dietary supplements, a deregulation of the dietary supplement market, so to speak. The DSHEA has three main components: "research, labeling, and standard of proof for safety."¹¹

As previously noted, the NLEA was interpreted by the FDA as requiring "significant scientific agreement" regarding labeling claims. The DSHEA requires the substantiation requirements for claims, but actually fails to define "the nature or scope of the requisite substantiation."¹² The Federal Trade Commission has sought to articulate the required standards for substantiation. It considers human and animal studies, *in vitro* data and traditional use information. These types of evidence may well be adopted by the FDA when

¹¹Kaczka, *supra* note 4, at 485.

¹²I. Scott Bass & Charles J. Raubichek, *Marketing Dietary Supplements* (2000) at IV-7.

it sets forth its requirements.¹³

Before the enactment of the DSHEA, the standard of proof regarding the safety of dietary supplements was adjudicated under the Federal Food, Drug and Cosmetic Act. If a dietary supplement was deemed unsafe under the Act, the Act imposed a burden on the manufacturer to “show that its ingredient was covered by a food additive regulation, or that the ingredient was not a food additive but instead was generally recognized as safe.”¹⁴ In addition to requiring rulemaking which defines adulterated supplement as posing a substantial and unreasonable risk and banning supplements which pose an imminent threat, the Act shifted the burden of proof concerning dietary supplement safety to the FDA rather than the manufacturer: “Manufacturers are responsible for providing information to support their claims and need not prove safety or effectiveness. Instead, under the DSHEA the FDA bears the burden of proving the products are unsafe.”¹⁵

The DSHEA also allows manufacturers to make certain kinds of statement on the label of dietary supplements, statements which do not need pre-approval from the FDA: “Those claims essentially allow a company to tell how a substance beneficially affects the way the body functions, how you maintain or support your immune system or the mechanism by how that dietary ingredient operates in your body. They can also take about general well-being claims.”¹⁶ The Act allows for statements addressing the effect of dietary supplements on the structure or function of the body. It does not, however, allow manufacturers to make so-called “disease claims”, statements which claim that a supplement treats or prevents disease: “... Congress has permitted dietary supplements to be intended to affect the structure or function of the body, but it has not permitted dietary supplements to be intended to treat, prevent, mitigate, cure, or diagnose disease, except that dietary supplements may bear authorized health claims.”¹⁷ The Act defines acceptable statements in

¹³*Id.*

¹⁴I. Scott Bass & Anthony L. Young, *Dietary Supplement Health and Education Act* (1996) at 44.

¹⁵Kaczka, *supra* note 4, at 488.

¹⁶*Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress?* *supra* note 3, at 83.

¹⁷*Id.* at 45.

the following manner:

...[A] statement for a dietary supplement may be made if –

(A)

(B)

Manufacturers are required to notify the FDA of statements made on labels within 30 days of marketing. As noted, the claims must be substantiated. Structure/function claims must also be accompanied by a disclaimer stating the following: This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.”

Although published after the passage of the DSHEA, the intent of Congress in passing the DSHEA is as follows:

DSHEA amended the Federal Food, Drug and Cosmetic Act (FD&C Act) to define the term “dietary supplement” and establish a regulatory framework for dietary supplements. In doing so, Congress made 15 significant findings that emphasize the importance of diet and nutrition, including dietary supplement use, in promoting health and reducing the risk of disease. FDA acknowledges these findings. DSHEA provides for broad access to dietary supplements for consumers and also recognized that there is a need for a rational regulatory framework that provides FDA authority to remove from the market products that pose a “significant or unreasonable” risk to consumers or that are otherwise adulterated and to require that labeling for dietary supplements be accurate.¹⁹

Congressional intent in deregulating the dietary supplement industry comes through loud and clear in the new labeling requirements. A manufacture simply must send a letter to the FDA when introducing a new product with a health claim and for new uses or a change in dosage recommendation. The FDA need not approve products or claims, offering essentially an un-checked ability for manufacturers to make claims and

allowing them to eliminate negative information required in the labels of over-the-counter (OTC) drugs. Regardless of the congressional intent implied in the new Act, “what Congress intended as a new safe harbor for dietary-supplement claims has been something of a minefield, thanks largely to an unfriendly attitude on the part of the [FDA].”²⁰

Implementation of the DSHEA

The FDA’s role in instituting the DSHEA is in the promulgation of regulations which could implement the Act. Rules promulgated to date include establishing a “Supplement Facts” requirement on dietary supplement labels (similar to the nutritional labeling on foods) and proposing rules for establishing “Good Manufacturing Practices” for manufacturers.

In April of 1998, the FDA published its proposed rule identifying the types of structure/function statements which could be made on a dietary supplement label under the DSHEA: “[The] proposed rule defin[ed] the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body.”²¹ This presented the FDA with the need to distinguish between structure/function claims and disease claims, which it had heretofore not addressed. The rule-making was intended to implement the portion of the DSHEA, as noted above, which allowed manufacturers to make structure/function claims and provide direction to the supplement industry with the types of statements which they could make

²⁰Greenberg, *supra* note 9.

²¹Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress?, *supra* note 3 at 39.

regarding the effects of supplements on the structure or function of the body. The FDA was attempting to provide this guidance and respond to information provided by the Commission on Dietary Supplement Labels (established by the DSHEA). The proposed rule attempted to clarify the types of statements which manufactures may make by distinguishing between permissible statements referring to the role of the dietary supplement in affecting the structure and function of the body and those which are impermissible disease claim statements. In developing the proposed rule, the FDA considered the following guidelines given by the Commission of Dietary Labeling to assist in differentiating structure/function claims and disease claims:

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- 1)

- 2)

- 3)

- 4)

- 5)

- 6)

7)

In presenting this rule, the FDA employs these guidelines to clarify permitted structure/function claims, defines disease, and establishes the criteria for identifying disease claims.²³

The FDA recognizes in its proposed rule that the DSHEA allows “the manufacturer of a dietary supplement [to] make a truthful nonmisleading labeling statement claiming that the product affects the structure or function of the body, unless the statement expressly or implicitly claims an effect on a disease....”²⁴ The proposed rule defines permitted structure/function claims in the following manner:

Under proposed § 101.93(f), dietary supplement labels and labeling may bear structure/function statements that are not disease claims within the meaning of proposed § 101.93(g) and that otherwise comply with the notifications and disclaimer provisions of § 101.93(a) through (e), including the requirement that any structure/function statement be substantiate.²⁵

The proposed definition of disease is more thorough than under previous acts, rules, and regulations, and, as it turned out, a controversial sticking point. Some claimed that the new definition would essentially prevent all structure/function claims on the labels of dietary supplements.²⁶ The FDA chose to formulate a definition which differed from the NLEA’s definition, a definition “based on standard medical and legal definitions of the term”²⁷: “Under the proposed § 101.93(g)(1), a “disease” is any deviation from impairment of, or interruption of the normal structure or function of any part, organ or system (or any combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms.”²⁸ In order

²³*Id.* at 23625-23636

²⁴*Id.* At 23625.

²⁶Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress? *Supra* note 3, at 69.

²⁷*Id.*

²⁸*Id.*

to avoid inconsistency, the FDA proposed an additional definition of “disease” or “health-related claim” under § 101.14(a)(6):

...[A disease or health-related condition is defined as] any deviation from, impairment of or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms (including laboratory or clinical measurements that are characteristic of a disease), or a state of health leading to such deviation, impairment, or deviation; except that diseases resulting from the essential nutrient deficiencies (e.g., scurvy, pellagra) are not included within this definition or §101.70).”²⁹

The FDA considered this change in the definition of disease because it found the NLEA’s requirement of “damage” to be so narrow as to not consider some conditions as diseases that are typically considered as so by the medical profession. In the proposed rule, the FDA notes that the proposed definition for § 101.14(a)(6) was broader than that proposed for § 101.93(g)(1). This definition proved critical as it distinguished the line between “disease claims” and “structure/function claims”³⁰ In noting the distinction, the Agency explains that the definition in § 101.14(a)(6) is intended to cover both diseases and “health-related conditions,” thereby requiring the expanded definition.³¹ Ironically, it is exactly that broadening of the definition of disease that creates the most controversy for the FDA’s proposed rule.

In its proposed rule, the FDA also defined the criteria for identifying a disease claim. The FDA provided illustrations of statements which it would and would not consider to be disease claims, with all statements considered in context. Proposed § 101.93(g)(2)(i) classifies a statement as a disease claim if it claims an “effect on a specific disease or class of diseases.” Examples of disease claims under the proposed § 101.93(g)(2)(i) include “‘protective against the development of cancer,’ ‘reduces the pain and stiffness associated with arthritis,’ ‘decreases the effects of alcohol intoxication,’ ‘or alleviates constipation.’”³² Examples of structure/function claims would include “‘helps promote urinary tract health,’ ‘helps maintain cardiovascular

³⁰Bass & Raubichek, *supra* note 12, at IV 5.

³¹52 Fed. Reg. 23624, 23626.

³²*Id.*

function and a healthy circulatory system,’ ‘helps maintain intestinal flora,’ and ‘promotes relaxation.’”³³ The FDA identifies these statements, at least preliminarily, as structure/function statements as they are broad and fail to refer to specific diseases.

The proposed rules then identifies statements which would and would not be acceptable under the proposed definition of disease (statements which explicitly or implicitly refer its effect on a disease or symptom) under § 101.93(g)(1) include “‘improves urine flow in men over 50 years old’ (characteristic symptoms of, e.g. benign prostatic hypertrophy); ‘lowers cholesterol’ (characteristic sign of, e.g. hypercholesterolemia); reduces joint pain’ (characteristic symptoms of, e.g., arthritis); and ‘relieves headache’ (characteristic symptom of, e.g., migraine or tension headache).”³⁴ As to the previous examples, it is the specificity of the symptoms mentioned that disallow these statements. Statements which would be allowable and considered structure/function statements (not referring to specific diseases would include “‘reduces stress and frustration,’ ‘inhibits platelet aggression,’ and ‘improves absentmindedness.’”³⁵ The prior statements are considered broad enough as to not refer to specific diseases. The FDA recognizes that “there can be disagreement about circumstances in which a reference to maintaining normal function implies disease treatment or prevention,”³⁶ and it sought comments on the issue.

The FDA next seeks to explain that claims made regarding natural states (e.g., aging, pregnancy) may be considered disease claims in some circumstances, a second, related issue raised in the proposed rules which raised a fire-storm of controversy. These states “are sometimes associated with abnormalities that are charac-

³³Id.

³⁴Id.

³⁵Id.

³⁶Id.

terized by a specific set of signs or symptoms, and thus meet the proposed definition of disease.”³⁷ Examples of disease claims under these criteria might refer to the symptoms of toxemia, premenstrual syndrome or Alzheimer’s disease. Acceptable structure/function statements would refer to conditions generally with no mention of specific abnormalities, signs or symptoms.

The proposed rule indicates that a variety of aspects of a product’s label may be considered, under § 101.93(g)(2)(iv), to be disease claims. Explicit or implicit claims may be made in a product’s name, by claims about its formation, by citing a publication in which the title names a specific disease, or use of the word disease, or “by use of picture, vignettes, symbols, or other means” which suggest an effect on a disease.

³⁸ The use of some product class names may be considered to be disease claims through association with a specific disease under the proposed rules: “[S]tatements would be considered a disease claim if it claimed that the product belonged in a certain class of products recognizable to health care professions or consumers as intended for use to diagnose, mitigate, treat, cure, or prevent a disease.”³⁹ A statement might also be considered a disease claim if it claims a similarity to a drug or disease treatment intended to treat a disease or if it suggests that the product should be used in conjunction with such a drug or disease treatment. These types of claims imply that the effect of the product is similar to that of recognized drugs or treatments, and are, therefore, to be considered disease claims. Claims which are general in nature, not mentioning a specific drug or therapy are, again, considered structure/function claims.

Other claims which would be considered disease claims under the proposed rules are those that suggest that a product can be used to enhance the body’s own natural “disease fighting capabilities.”⁴⁰ Under this criterion, a statement would be considered a disease claim if it refers to a normal bodily response to disease

³⁷*Id.* at 23627.

³⁸*Id.*

³⁹*Id.*

⁴⁰*Id.*

or the bodily ability to prevent or mitigate the effects of an infectious disease or pathogen. Acceptable structure/function claims may refer to a generalized bodily system with a variety of functions.

Additionally, statements which claim an effect on side effects of drugs or disease treatments are also considered disease claims. These claims are interpreted under the proposed rule because, similar to a claim which suggests a product should be used in conjunction with a drug or disease treatment, these types of claims infer that they should be used in the initial treatment plan for a disease. The mere mention of a therapy for a disease makes a statement a disease claim, while claims which do not mention a therapy do not. Finally, the proposed rules include a “catch-all” category which states that “[u]nder proposed § 101.93(g)(2)(x), a statement would be considered a disease claim if it otherwise suggested an effect on a disease or a class of diseases.”⁴¹ The inclusion of this final criterion for identifying disease claims leaves the FDA with a good deal of wiggle room in its ability to broadly define the characteristics of disease claims.

As required when promulgating regulations, the FDA included the typical citation of legal authority, the effective date of the proposed rule and its plan for implementation, an environmental impact statement, a statement on the expected economic impact of the proposed rule (cost-benefit and small entity analyses) and a request for comments.

Reaction to the Proposed Rules

Reaction to the proposed rule was swift and harsh. The FDA was inundated with over 100,000 comments (all of which it was obligated to take into account) from the public, manufactures, academics, medical professionals attorneys and other interested parties. Based on these reactions, there was also a general

⁴¹*Id. at 23628.*

outcry in professional journals and other publications. The Committee on Government Reform in the House of Representatives held a hearing on March 25, 1999 to determine whether the FDA was attempting to thwart Congress, intent in passing the DSHEA with its proposed rule

Congress' Intent

Critics have noted various attempts by the FDA to thwart Congress' intent in implementing regulatory structures for dietary supplements. The Proxmire Vitamin Mineral Amendment of 1976 stated that the FDA may not establish maximum limits on vitamins or mineral potency, classify a vitamin or mineral as a drug based on its potency, or limit combinations of vitamins or minerals. However, [a]lthough [the amendments were] significant for establishing a precedent, the 1976 amendments had little impact on the FDA's aggressive regulations of dietary supplements."⁴² Similarly, the NLEA allowed the FDA to pronounce the regulations of health claims. The FDA, in implementing the Act, established that the requirements of health claims would be the same for conventional foods and supplements, consequently disabling Congress' attempt to loosen the regulation of dietary supplements. The DSHEA was Congress' reaction to this regulatory effort, which both incapacitated the FDA's regulations and sent a clear message of the congressional intent to restrict the FDA under the NLEA.⁴³

As noted above, the FDA's proposed rules garnered intense scrutiny in Congress. The House of Represen-

⁴²Kaczka, *supra* note 4, at 475.

⁴³Dietary Supplement Health and Education Act: Is FDA Trying to Change the Intent of Congress? *Supra* at note 3, 23628.

tatives held a hearing in March of 1999 entitled “Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress?” As could easily be divined from the title of the hearing, the Committee sought to discover whether the FDA, in its implementation of the DSHEA was thwarting Congress’ intent as indicated by the DSHEA.

The topics of discussion at the hearing were varied. The Committee discussed issues such as the FDA’s promulgated rules regarding nutrition labeling, the FDA’s lack of attention to good manufacturing standards, authoritative health claims, recent court decisions, and specific supplements which raised the concern of Congress. For our purposes, the Committee’s discussion of the FDA’s proposed rules regarding structure/function statements is of the greatest import. Congress’ concerns are summarized as follows:

In April, 1998, the FDA published a proposed rule defining the types of statements that can be made concerning the effect of dietary supplements on the structure or function of the body. This is one of the cornerstones of the Dietary Supplement Health and Education Act which allows for statements on structure and function, but prohibits claims that supplements treat or prevent disease. The agency received over 100,000 comments regarding this issue which clearly indicates the proposed regulation is fraught with problems. Of particular concern is that the FDA redefined the word disease” in such as [sic] manner that it could include conditions such as aging, menopause, and pregnancy. This new definition so broadens the definition as to exclude any useful structure function statements. If this rule became final, it would be in direct contradiction to the Dietary Supplement Health and Education Act’s intent of improving the amount of information available on labels and in labeling.⁴⁴

Of particular interest, in this statement, is that Congress has foreshadowed, so to speak, the future of the FDA’s proposed rule on structure/function claims.

The hearing focused on the proposed rule on structure/function claims. In Congress’ view, its intent in passing the DSHEA was to allow dietary supplement manufacturers to make such structure/function statements in order to better inform the public about the benefits it can expect in consuming a product which will

support the structure or function of the body. The introductory statement of the hearing noted that: [t]he proposed rule would supersede legislation passed by the Congress and be in direct opposition to the will of Congress and the American people.” In a rather responsive statement, one commentator noted that “[w]hile some have argued that DSHEA is full of complex questions of fact, policy and law, it is the duty of the FDA and its Commissioner to enact DSHEA and provide the American consumer with safe and regulated dietary supplements.”⁴⁵ Some members of the Committee even suggested that the “FDA is deliberately suppressing information which could help health consumers make an educated decision about products which could help them. The FDA limits what producers of health supplements may say about their products.”⁴⁶

Attorney Scott Bass, a noted expert on food and drug law, sets out four basic points which criticize the FDA’s proposed rule for attempting to thwart the intent of Congress:

A.

FDA proposes to redefine the word “disease” so that “disease” would be defined as any interruption or impairment of “normal structure or function.... During the negotiation leading to the passage of DSHEA, there were some efforts to insert the word “normal” in the structure/function section. Those efforts were met with strong resistance and Congress chose to leave it out. For this reason alone, the proposed regulation significantly undercuts the benefit of Section 6.

B. The new “disease claim definition can make almost any claim illegal.

... FDA’s redefinition of “disease claims” renders a dietary supplement illegal if a product claims an effect on “one or more signs or symptoms constituting an abnormality of the body.” It is not difficult to imagine that some symptoms might be “recognizable to health care professionals” as referring to normal or *abnormal* people – e.g.[.], a pregnant woman, a woman enduring menopause, an aging individual or a person with allergies.

⁴⁵*Id.* at 25.

⁴⁶*Id.* at 59.

C.

... All the FDA has to prove is that a health care professional “recognizes” that a dietary supplement claim “implicitly... has an effect on a consequence of a natural state” that the health care professional thinks is an implicit reference to an abnormality.... [I]n practice, [that] means the defendant loses. If the FDA obtains the affidavit of one health care professional, the Agency would carry the day....

D.

that the product had not been approved by FDA and was not intended to treat or cure disease. The proposal

Clearly, Mr. Bass considers the proposed rule as an attempt by the FDA to frustrate the entire congressional motive for passing the DSHEA, to provide the public with much needed information in a blossoming dietary supplement market. Others made similar claims: “The current proposal appears to be a stubborn attempt to reverse the major provisions of DSHEA and prevent most statements of nutritional support.”⁴⁸ Further, “Congress specifically rejected limiting structure/function claims to the ‘help maintain’ or ‘promote healthy’ structure/function variety when it enacted DSHEA. Rather Congress intended to permit claims that describe the role a nutrient plays in the body.”⁴⁹ Similarly, the proposed rule would disallow some claims about natural states of being, considering them disease claims, while Congress intended these types of statements to be permissible.⁵⁰

Criticism of Proposed Rule

⁴⁸*Id.* at 117.

⁴⁹*Id.*

⁵⁰*Id.*

Congress saw the proposed rule as a “regulatory sleight-of-hand to stifle such statements.”⁵¹ It was clearly a difficult thing to draw the line between structure/function claims and disease claims under the DSHEA, but some felt that “[i]t [was] even more complicated [when] the FDA, historically biased toward thinking things are drugs, proposed implementing regulations that defined “disease” broadly, making it harder to formulate a structure function claim that is permissible.”⁵² Others suggested that the “agency proposes to do through administrative fiat that which Congress refused to do expressly, limit structure/function claims to “maintaining” or “promoting” healthy bodily structure or function claims.”⁵³ These comments focused on the fact that, while the DSHEA requires a distinction to be drawn between structure/function claims and disease claims and that such a distinction may be difficult to make, the FDA failed, in fact, to draw such a clear distinction between these types of claims.

One critic noted that the FDA had not furnished any legal basis supporting its authority to change the definition of disease in its proposed rule.⁵⁴ Another noted that the FDA’s actions seemed to be a mere power grab.⁵⁵

An additional criticism of the rule’s labeling requirement focuses on the sheer difficulty in overcoming regulatory-induced dilemma presented to manufacturers in the proposed rule: “FDA establishes a “consumer intent of use” basis for reclassifying a dietary supplement as a drug based on how a consumer intends to use a product – even if it is properly labeled with an allowable structure/function statement.”⁵⁶

Most of the 100,000 comments and focused on the FDA’s re-definition of “disease.” (The FDA received an additional 200,000 consumer letters critical of the proposal).

Criticism of the proposed re-definition of disease also came from other sources. For example, in a letter from

⁵¹Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress? *supra* note 3, at 69.

⁵²Greenberg, *supra* note 9.

⁵³Todd Harrison, “FDA Continues to Struggle with the Permissible Breath of Structure/Function Claims. Definition of Disease Still Subject to Debate.” <http://www.khlaw.com/nutra/html>. (7/15/00) at note 48.

⁵⁴Dietary Supplement Health and Education Act: Is FDA Trying to Change the Intent of Congress? *Supra* note 3, at 120.

⁵⁵*Id.* at 122.

⁵⁶*Id.* at 123.

Representative Daniel Burton to Michael Friedman, Representative Burton suggested that the definition is too broad and would include statements made about some natural states would be considered disease claims under the proposed definition.⁵⁷ Other critics note that: “[t]here is no such thing as a normal body’ and because ‘[v]irtually anything is a deviation from a normal body,’ a literal interpretation of this definition would effectively mean that ‘there [is] no such thing as a structure/function claim’ and that all claims are disease (drug) claims.”⁵⁸

In response to the concerns regarding the re-definition of disease, the FDA held a panel discussion about whether the definition was adequate. The panel was held on August 4, 1999, revealing a division between interest parties on the topic of whether “damage” should be an issue in defining disease. Some recognized that the new definition of disease differed considerably from that of the NLEA by deleting of damage which interferes with proper functioning requirement, requiring a mere deviation. These panelists showed concern about the deletion of the damage requirement because any deviation from normal functioning, even if natural or otherwise short-lived could be considered a disease. Others took an opposite view that the definition was not broad enough, that it discounted deviations that were not typical of disease, but nonetheless, typically may require medical attention (e.g., constipation) and that many conditions, in their early stages would not meet the FDA’s definition of disease. Still others were concerned about the protection offered to consumers by the new definition. This panelist focussed on a definition which would disallow claims if consumers were unable to adequately evaluate them.⁵⁹ Most panelists agreed that the severity of a condition should not be the criteria which determines the type of claims which can be made under the structure/function criterion. Some panelists felt that the typicality of an association of a symptom with an associated pathology would be a better test than severity (some noting, however, that even this test may rule out some conditions which

⁵⁷Michael Cohen, *U.S. Dietary Supplement Regulation: Belief Systems and Legal Rules*, 11 *Hastings Women's L.J.* 3, 21 (Winter, 2000).

⁵⁸Laura A.W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 *Food & Drug L.J.* 623, 639 (2000).

⁵⁹Richard O. Wood, Erik F. Dyhrkopp & Andrew H. Kim, *Panel Debates New Dietary Supplement Regulations*, 11.29.99 *Nat'l L. J.* B12. (col. 1).

can be considered disease). Finally, panelist discussed their concerns regarding the FDA's effort to clarify what would be considered an implied disease claim. The FDA offered examples of implied claims in the proposed rules, but the panelists had difficulty distinguishing between the examples offered.⁶⁰ The panelists seemed to reflect similar concerns as put forth in the comments written to the FDA.

Still others criticized the examples of acceptable statements offered by the FDA, finding them rather silly: "Thanks to 'clarification' by federal regulators, consumers of dietary supplements will have better information when they seek 'to improve their absentmindedness' or 'maintain their healthy intestinal flora'.... [S]ome of the FDA's examples are bound to keep manufacturers and consumers alike at least as confused as before, if not more so."⁶¹ Some of the examples require "mental gymnastics" to understand while others are actually incomprehensible.⁶² The examples offered are, at times inconsistent or ambiguous to the extent that they belie their purpose, to provide guidance to manufacturers.

Other critics called the criteria for differentiating between a claim of health promotion and a statement claiming disease prevention capabilities were too narrow and potentially misleading:

FDA's examples of "lowers cholesterol" versus "helps maintain a healthy cholesterol" highlight the ambiguities inherent in FDA's proposed construct of disease claims under proposed criteria #2 and #3. What is healthy cholesterol, but a lower cholesterol level? The FDA-defined disease-related endpoint is a lowering of, presumably, a higher cholesterol level; the health-related endpoint is maintenance of a "healthy" cholesterol level – which itself is a "lower" cholesterol level generally recognized as the goal of disease prevent.⁶³

Part of the problem may be that the regulations are to apply to both vitamins and herbal remedies, even though they may be used for very different purposes: "[T]rying to fashion a one-size fits all solution for an industry with very different types of products does not work."⁶⁴

⁶⁰Id.

⁶¹Michele Simon, *Still Cloudy with Little Chance of Clearing: FDA's Proposed Rule on Structure/Function Claims for Dietary Supplements*, 11 Hastings Women's L.J. 23, 23-24.

⁶²Id. at 24.

⁶⁴Simon, *supra* note 62 at 25.

Focusing on the product's intended purpose brings another criticism: "There is simply no getting around the reality of consumers turning to dietary supplements for treatment-related purposes. The FDA's attempt to bury its head in the sand and pretend this is not happening because manufacturers are not allowed to label or market [their] products as such is both irresponsible and futile."⁶⁵

Supporters of the Proposed Rule

On the other hand, some members of the Committee provided support for the FDA's actions:

Today we will hear arguments that Congress did not intend for the FDA to have an active role in protecting the consumer from dangerous products being sold as dietary supplements. We will also hear that FDA's recent efforts to protect the consumer are inappropriate and heavy-handed intervention. This is simply erroneous. When we passed DSHEA, we knew that many dietary supplements, such as minerals and vitamins, can play an important role in promoting health. But, we also know that, without proper regulation, dietary supplements can sometimes be lethal.⁶⁶

The commentator continued with the idea that "the agency is trying its best to implement a complex and ambiguous law."⁶⁷

Rather than criticize the FDA's efforts, the supporter has a suggestion to ameliorate the controversy: "The answer isn't to criticize the agency for failure to adhere to the intent of Congress when, in fact, the agency is trying its best to implement a complex and ambiguous law. Instead, the answer is to establish a regulatory framework for dietary supplements at FDA that appropriately balances the interests of consumer access and public health."⁶⁸ Still another claimed that the proposal's criteria for making structure function claims was

⁶⁵Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress? *Supra note 3 at 123.*

⁶⁷*Id. at 18.*

⁶⁸*Id. at 18.*

too narrow [implying that the FDA's efforts were appropriate: "General references to bodily functions can still imply usefulness to prevent disease conditions, and especially so when the claims refer to bodily organs and functions that normally receive medical attention."⁶⁹

These supportive comments reflect early criticism of the DSHEA and its attempt to deregulate the dietary supplement market. Critics complain that "'DSHEA has severely limited FDA's power over vitamin safety and the validity of benefit claims.... Congressional removal of most FDA enforcement powers in the 1994 DSHEA has wiped out the FDA's power to require preapproval and claim substantiations and has sharply reduced regulators' options."⁷⁰

Final Rule

In publishing its final rule entitled "Regulations on Statements Made for Dietary Supplements concerning the Effect of the Product on the Structure or Function of the Body," the FDA noted that in publishing its proposed regulations to identify and distinguish structure/function claims and disease claims, it received over 235,000 responses to the proposed regulations. Most of the submissions were form letters, but 22,000 individual letters were submitted from "the dietary supplement industry, trade association, health professional groups and consumers."⁷¹ Most of the general comments objected to the proposed regulations, stating that the regulations were too confining. Those who approved of the proposed regulations (mainly health care professions) felt that the rules were impartial and fair, although some recommended more restrictive regula-

⁶⁹Id. at 138-139.

⁷⁰James T. O'Reilly, *Dietary Supplement Regulation Constrained by Political Chains*, 8-WTR Experience 20, 21 (Winter, 1998).

⁷¹Regulations on Statements Made for Dietary Supplements concerning the Effect of the Product on the Structure or Function of the Body, 21 CFR Part 101, 65 Federal Register, 1000 (200).

tions.⁷² Although, in publishing its final rule, the FDA discusses and responds to hundreds of the comments, we will focus on specific areas for our purposes, specifically, the general comments structure/function statements, the definition of disease, disease claims, the effect on a disease or class of diseases, signs a symptoms of disease, conditions associated with natural states

In regard to general comments, many that were critical of the proposed regulations felt that “the proposed rule would curtail or restrict [truthful information] or restrict the focus of dietary supplements to preventive care and wellness....”⁷³ These commentators focused on choice, consumer responsibility, autonomy, self-education and suggested that a different standard “a ‘truthful and not misleading’ standard” or a “full disclosure” standard.⁷⁴ Others were concerned that the proposed rules would lead to confusion and less information would be available to consumers, contrary to Congress’ intent. These commentators said the new regulations would prevent harm, misinformation, suffering, monetary loss and may produce a false sense of security, making consumers unlikely to seek or maintain medical support.⁷⁵ The FDA agreed that many of observations were valid, but maintains that the DSHEA did, indeed, advance Congress’ intent of providing consumers information regarding dietary supplements and notes that the final rule allows some of the statements which would have been disallowed under the proposed rules to be made without pre-approval. The FDA also notes that manufactures are subject to a “truthful and not misleading” standard elsewhere in the rules, so adoption of that standard is unnecessary.

Other comments spoke on the issue of safety of dietary supplements. Many claimed that regulations regarding labeling of dietary supplements are really unnecessary, as the supplements themselves are safe. Other, however, noted that dietary supplements might give consumers a false sense of security, perhaps leading to dangerous results. The FDA agrees that safety is the motivation behind the rule and that mislabeling

⁷²*Id.*

⁷³*Id.* at 1002.

⁷⁴*Id.*

⁷⁵*Id.*

poses a risk to consumers. Additionally, although the FDA regards many dietary supplements as safe, it recommends further studies to determine the safety and effectiveness of some supplements.⁷⁶

The comments reveal an addition charge that the “FDA had no authority to issue the proposed rule because it was inconsistent with DSHEA and congressional intent, in that it restricted rather than increased the amount of information given to consumers.”⁷⁷ As noted in the discussion above, many feel that Congress passed the DSHEA as a result of the FDA’s over-regulation of dietary supplements. The FDA agrees that Congress’ intent regarding the DSHEA was to allow for more information to be offered to consumers, and points to changes in the final rule which address these concerns, “including a return to the preexisting definition of “disease or health related condition” and a less restriction interpretation of the types of structure/function claims that can be made about conditions associated with natural states such as aging, pregnancy and the menstrual cycle.”⁷⁸ The FDA does note that separate authority is not required for the promulgation of the rule, and it also reiterates the fact that disease claims are still reviewable under the final rule.

Still others claim that the FDA did not adequately justify the basis for issuing the rule. Some argued that the FDA did not adequately consider the Commission’s report when developing the proposed rule and that the DSHEA is self-implementing. The FDA counters that under 701(a), it did have the authority to issue the rule and bases this claim on the fact that sufficient confusion exists among consumer and manufacturer confusion exists to justify the promulgation of the rule, and hence, the DSHEA is not self-implementing. The FDA also notes that the Commission’s support of the proposed rule was not necessary.⁷⁹

One comments notes that the proposed rule should have been crafted in a manner to avoid overlaps between structure/function claims and disease claims, but the FDA responds that while some statements, on their face, may resemble structure/function claims, they are, in essence, disease claims, so there can be no concrete

⁷⁶*Id.* at 1003.

⁷⁷*Id.*

⁷⁸*Id.* at 1003-1004.

⁷⁹*Id.* at 1004-1005

distinction.⁸⁰ Others agree that it is not possible to draw such a distinction, and the FDA notes that its efforts are statutorily required.⁸¹

Some commentators feel that the rule would chill scientific research, but the agency says there is no evidence to support this claim. Still others feel that the proposed rule would impact drug development, some feeling that it was a pro-pharmaceutical action, while others feel it would have a negative impact on development of such products. The FDA also disagrees with this charge.

Additional comments demonstrate concerns that dietary supplements may be classified as drugs if the statements made on the label, or other evidence, could be considered by consumers to be disease claims. The FDA applies that such evidence is not considered in isolation. Consumer intent alone would not be used to classify a dietary supplement as a drug.⁸²

Other commentators express concern about the disclaimer requirement under the proposed rule. While some feel that the statement resolved consumer confusion, others felt that the disclaimer was inconsistent with the proposed rule (in that a disclaimer is not necessary if the proposed rule so limits structure/function claims as to make them unavailable). The FDA disagrees, saying “the disclaimer’s role does not eliminate the need for this final rule to establish criteria for determining whether a statement is a disease claim.”⁸³

Some comments seek additional labeling requirements for dietary supplements, although while the FDA states that the Act sufficiently addresses these concerns. The FDA also refers to its consistent use of the term claims and “statements” as equivalent despite concerns that the term “claim” may be pejorative.⁸⁴ Still others demonstrate concern that unless some supplements were classified as drugs, non-reviewed potency levels and the lack of scientific evidence of safety raise concerns about the harmful effects of essentially unregulated supplements. However, despite the tone of the proposed rule, the FDA asserts that some “health-

⁸⁰*Id.* at 1005.

⁸¹*Id.*

⁸²*Id.* at 1006

⁸³*Id.* at 1007.

⁸⁴*Id.*

related” claims are acceptable under the structure/function claim criterion.⁸⁵

Still other comments complained that the proposed rules criterion were too subjective. The FDA responds by modifying one of the criteria to a more objective standard.⁸⁶ Others object to the regulation of any statement or claim which referred to a “nutrient content claim or claims pertaining to a classical nutrient deficiency-related disease.”⁸⁷ In addressing this concern, the FDA states that the final rule already provides an exception to claims which refers to a classical nutrient deficiency disease. Many suggest that the FDA should issue guidance documents in lieu of the proposed rule. The FDA disagrees, noting that the regulations provide uniform requirements to all members of the industry. Another solution is offered to the FDA to merely enforce existing laws which focus on supplement safety, rather than promulgate regulations. However, the FDA notes that regulations provide a valuable tool in the regulation of dietary supplements.⁸⁸

Other alternatives to promulgating regulations are made. Others suggest that the FDA lacks the expertise to classify botanicals, and others pointed to the regulation of dietary supplements in other countries as an alternative. The FDA, in rejecting these ideas, also notes that the FDA would be issuing guidance documents to address many of these concerns.⁸⁹

The FDA provide no response to comments discussing the issue of permitted structure/function claims, noting that it had modified § 101.93(f) “to make it clear that a dietary supplement may bear a disease claim if it is the subject of an authorized health claim, but that otherwise disease claims will subject the product to treatment as a drug.”⁹⁰

The FDA proposed definition of disease in § 101.93(g)(1) results in many comments. The FDA re-opened the comment period, and sought additional comments on the following issues:

⁸⁵*Id.*

⁸⁶*Id. at 1007-1008.*

⁸⁷*Id. at 1008.*

⁸⁸*Id.*

⁸⁹*Id. at 1008-1009.*

⁹⁰*Id. at 1009*

(1)

(2)

(3)

(4)

Nearly all comments protest the proposed definition of disease, many calling it too broad. Some suggest that changing the definition clearly frustrated congressional intent.⁹² Other comments suggest a return to the 1993 definition, but those in the medical community supported the new definition. Others suggest a different definition altogether (seemingly following the interests of the group to which they originate) or advocated a “common sense” approach. In response to the to be negative comments, the FDA concludes that the 1993 definition would not exclude any disease conditions, and, as such, declined to enter a new definition of disease in the final rule.⁹³ Another suggests that the definition should be crafter so as to not include health-related conditions which do not require drug or medical treatments. The FDA responds that there is no congressional intent demonstrated which would call of subsets for diseases to be established. Finally, another commentator suggested that the 1993 definition fit well with consumer understanding.⁹⁴

⁹²*Id.*

⁹³*Id. at 1010.*

⁹⁴*Id. at 1010-1011.*

As to comments discussing disease claims under § 101.93(g)(2), many comments agree that a claim should be examined in the light of total circumstances. Others feel the rule was biased or vague. The FDA recognizes competing goals in the comments and states that the final rule attempts to address these competing goals. Another comment suggest a rule which draws a correlation between the effects of a dietary supplement on a condition and the effects of a conventional food on the same condition, but the FDA notes that the claims should be product specific. Another suggests that any claim should be allowable which is not already considered a drug claim. The FDA counters, however, that not all drug claims are disease claims, so this distinction is not appropriate.⁹⁵ Finally, others suggest that the claims permitted under the proposed rule could not be substantiated. The FDA agrees that this applies to some claims, but believes that such claims fall within the scope of the provision and notes that substantiation of such claims would not be impossible.⁹⁶ Numerous comments focus on the effects on disease or class of diseases under § 101.93(g)(2)(i) which proposed that a claim would be considered a disease claim if it claims effects on disease. The FDA had sought additional comments on this issue during a public hearing concerning this section, offering examples of claims to be commented upon. It also four questions in response to the examples:

(1)

Many of the resulting comments feel that structure/function claims should, indeed, not mention diseases, citing consumer confusion and danger. But, others contend that implied disease claims should be allowed

⁹⁵*Id.* at 1011.

⁹⁶*Id.* at 1012.

if they are truthful, arguing congressional intent or the narrowness of the proposed rule. In response, the FDA notes that its stance has not changed, that implied disease claims should be disallowed, citing congressional intent: “Congress did not... create any exemption from section 201(g)(1)(B) of the act for dietary supplements. Thus, dietary supplements that are ‘intended for use in the ‘diagnosis, cure, mitigation, treatment or prevention of disease’ are subject to regulation as drugs under the act,”⁹⁸ the intent mentioned being an objective one. Allowing implied disease claims to be structure/function claims would both belie the FDA’s interpretation of the provision and would also “conflict with the health claim scheme established [by the act].”⁹⁹ The FDA cites case law and statutory provisions to support its view, asserting that those cases cited in the comments fail to support the suggestions offered. It also is not persuaded by the commentators’ interpretation of congressional intent or the intent of the Commission, as indicated by the totality of the act and the Commission’s report. The FDA also disagrees with some comments which suggest that the disclaimer provision shows a congressional intent to allow for implied claims, noting that the required language in the disclosure would be inconsistent or contradict with an implied claim.¹⁰⁰ The FDA responds that there is no evidence of this in the construction of the act and no consumer research to support such a conclusion. Others, as previously noted, suggest that under the proposed rules, it would be impossible to write an acceptable structure/function claims, and the FDA points to its examples in response. Some comments insist that the examples for disease claims discussed states, such as intoxication, which cannot be considered diseases. The FDA notes that intoxication is a form of poisoning and, thus, can be considered a disease. Finally, the FDA notes that the use of a professional organization’s endorsement (which contains the name of a disease) would result in a disease claim based on the totality of the labeling.¹⁰¹

The FDA then addresses § 101.93(g)(2)(ii) regarding signs or symptoms of disease. The section classifies

⁹⁸*Id.* at 1014.

⁹⁹*Id.*

¹⁰⁰*Id.*

¹⁰¹*Id.* at 1015.

claims as disease claims if they refer explicitly or implicit to signs or symptoms typically associate with a disease. Objecting comments claim this proposal is also vague. They were concerned that the rule refers to consumer recognition of a sign or symptom associated with disease. Some note that this would make comments a “moving target” subject to changing consumer information. The FDA responds by offering a more objective criterion in the final rule. The final rule eliminates the recognition requirement and replaces it with a criterion which asks “simply... whether the labeling suggests that the product will produce a change in the characteristic signs or symptoms of a specific disease or class of diseases.”¹⁰² The FDA notes that this test makes it easier to recognize what will be considered a sign or symptom.

Others argue that all signs or symptoms can be recognized as relating to a disease, especially for health care professionals. Others feel them to be arbitrary. Still others say signs or symptoms can be related to a number of conditions, not only diseases. The FDA points to the final rule (as noted above) which deletes reference to recognition to address these concerns. Others (some of whom object to the disease definition) say that merely because a sign or symptom is named in a disease definition, it does not follow that mentioning the sign or symptom in a claim should make it a disease claim, noting that the same does not hold for drug claims. The FDA argues that the definition of disease in the final rule does not refer to signs or symptoms, but claims that mention them will still be considered disease claims. The FDA also notes that the mention of the sign or symptom in the definition of a certain disease does not change the objective criterion it will use.¹⁰³

Other comments complain that the line between maintaining a healthy function and treating abnormal function is “artificial,”¹⁰⁴ that consumers make no such distinguish. Some insisted both types should be allowed while others (health professional) said that neither claim should be allowed. The health professions

¹⁰²*Id.* at 1006

¹⁰³*Id.* at 1007.

¹⁰⁴*Id.*

want claims which implied the prevention or treatment of disease to be considered disease claims (some suggesting that such statements would hamper the development of orphan drugs by undercutting the sales of such drugs). The FDA cites congressional intent by pointing out that the statute does distinguish between maintains healthy function and treats abnormal function claims. The FDA does maintain that the DSHEA considers abnormal function claims to be disease claims.

Other comments note that the FDA had not established the distinctions between the structure/function examples and disease claim examples it had offered, citing the cholesterol examples. The FDA said the mention of cholesterol in a claim would not classify it as a disease claim if it was a maintenance claim that makes no mention of “lowering” cholesterol, as cholesterol plays a positive role in the body. The FDA points at congressional intent again. Another comment expresses the opinion that “lowers cholesterol” claims should be allowed to provide the public with information on effective alternative, but the FDA believes this would pose a risk as some consumers may delay medical treatment. The FDA maintains that it had the experience and extensive evidence to support its decision.¹⁰⁵

The comment section included a lengthy discussion of constitutional issues involved in the proposed regulations. For our purposes, the discussion of First Amendment issues is especially enlightening. Some comments claim that “the rule violates the First Amendment because it is more restrictive than is necessary to advance FDA’s interests”¹⁰⁶ (see below for further discussion of this issue). These comments noted that the FDA may not prohibit statements which are not misleading, and the government may only regulate to the extent necessary to advance its interests. Because not all structure/function claims are false and misleading, this may overcome the FDA interests, even though substantial, claim these comments. Others claim the disclaimer requirement violates free speech rights.

Others focus on another issue: “[T]he proposed rule violates the First Amendment because, using the anal-

¹⁰⁵*Id.* at 1019.

¹⁰⁶*Id.* at 1037.

ysis in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), it is not narrowly tailored to meet the FDA’s interests and does not directly or materially advance the agency’s interests.”¹⁰⁷ Others are concerned that the FDA had failed to identify adequately its interests or shown that any of the claims were misleading. Some comments suggest that the proposed rule represent a “prior restraint” on free speech. Still other comments claimed that the proposed rule is contrary to the holding in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). According to the comment, “*Pearson* requires the agency to permit health claims that do not satisfy the ‘significant scientific agreement’ standard as long as the claim can be rendered non-misleading by requiring a disclaimer.”¹⁰⁸ This comment suggests that the FDA had no authority under *Pearson* to issue the final rule without modification.¹⁰⁹

The FDA responses to these comments are lengthy. It vigorously deny that the rule violates the First Amendment: The rule does not prohibit any speech; rather, it clarifies the circumstances under which FDA will consider certain types of speeches – labeling claims – to be evidence of intended use as a drug.”¹¹⁰ The FDA cites *Wisconsin v. Mitchell*, 508 U.S. 476 (1993) to support its contention that the Constitution does allow it to engage in evidentiary use of speech in proving intent.

Additionally, the Agency notes that even if the regulations did restrict speech there would still be no issue under the First Amendment. The failure of the FDA to enforce this rule and the failure of manufacturers to follow would create a situation in which unregulated products which could be considered drugs without the approval process for drugs, an illegal act in itself. The FDA concludes that, as such, free speech rights would not attach to an illegal product according to the Supreme Court in *Central Hudson*.¹¹¹

Nor does the FDA consider the rule to be a prior restraint on speech as it notes above; it is not restricting speech but using it as evidence of intent. The Agency acquiesces that some claims classified as disease

¹⁰⁷*Id.*

¹⁰⁸*Id.* at 1038.

¹⁰⁹*Id.*

¹¹⁰*Id.*

¹¹¹*Id.*

statements are subject to preapproval, including the evaluation of the product's safety and the supporting evidence for the claim. Additionally, in *Central Hudson*, the Supreme Court suggested that prior restraint may not even apply to commercial speech, and permitted the prior review of commercial speech.¹¹² (The FDA eventually concludes that the rule holds under all prongs of the *Central Hudson* test.)

The FDA goes on to discuss judiciary support of its regulatory schemes in a number of cases. The FDA particularly disagrees with the comment which requested no test for claims if accompanied by the disclaimer in order to improve the information available to consumers. The FDA's stance is that contradictory statements are more likely to lead to confusion.¹¹³ A scheme which allows disease claims to be reviewed (rather than merely accompanied by a disclaimer) ensures that an agency with relatively little bias will review these claims in order to support the government interest of consumer safety, according to the FDA.

The FDA dismissed the *Pearson* decision as inapplicable to drugs (although, interestingly it cites a footnote). It does give a little more attention to the holding in *Washington Legal Foundation v. Henney*, 1999 WL 557679 (D.D.C. July 28, 1999), which "concerned the constitutionality of certain provisions of the FDA Modernization Act of 1997."¹¹⁴ In this case, the subject matter involved the dissemination of information concerning "off-label" uses for currently approved drugs. The court found the restrictions to be unconstitutional.¹¹⁵ The FDA notes it is appealing this case.

The FDA distinguishes *Washington Legal Foundation* by noting in that case: 1) there were less restrictive alternatives, which would advance the government's interest; 2) the language in that case was directed only toward physicians, not the general public; and 3) the products involved in that case *were* drugs.¹¹⁶

Other constitutional claims include equal protection under the 14th Amendment and the Takings Clause

¹¹²*Id.* at 1038-1039.

¹¹³*Id.*

¹¹⁴*Id.* at 1040.

¹¹⁵*Id.*

¹¹⁶*Id.*

under the 5th amendment.¹¹⁷ The FDA points out that the 14th Amendment applies only to the states, but if the comment was intended to speak to the 5th Amendment, it notes that the comment fails to demonstrate disparate treatment, and the rule does not effect fundamental rights.¹¹⁸ As to the Takings Clause, the FDA notes that the test employed by the Supreme Court which examines the character of the government action, the economic impact of the action and the interference of the reasonable investment-backed expectations, would demonstrate that the rule can not be considered a taking under the Constitution.¹¹⁹

Further discussion is included referring to product names and formulations, citation of publication titles, the use of the word disease in a label, pictures and other symbols on a label, membership in a product class, substitutes for or augmentation of disease therapy, and the role of the supplement in the body's response to disease. These discussions also consider the treatment/prevention of adverse events, claims not addressed in the proposed rule, substantiation of claims, enforcement issues and a lengthy discussion of legal authority. The FDA supports its rule under all of these suggestions.

In short, after reviewing the comments, the FDA made revision in the final rule which offered the criteria for identifying when a labeling claim is a structure/function claim and when it is a disease claim. Specifically, in addressing the concerns of the comments, the FDA notes (as previously deleted its proposed definition for disease. Secondly, the FDA modified its criterion "that applies to conditions associated with such natural state or processes as menopause, aging, adolescence, and pregnancy...[such c]ommon conditions that do not cause significant or permanent harm will not be treated as diseases under the final rule"¹²⁰ Finally, the FDA revised the "criterion that relates to the use in labeling of the titles of publications that refer to diseases....

¹¹⁷*Id.* at 1040-1043.

¹¹⁸*Id.* at 1041.

¹¹⁹*Id.* at 1041-1043.

¹²⁰*Id.* at 1000.

Under the revised criterion, the use in labeling of a publication title that refer to a disease will be considered a disease claim only if, in context, it implies that the product may be used to diagnose, treat, mitigate, cure or prevent disease.”¹²¹ All of these changes are reflected in the Agency’s final rule, as follows:

PART 101—FOOD LABELING

* * * * *

§ 101.93 Certain types of statements for dietary supplements.

* * * *

(f) *Permitted structure/function statements.* Dietary supplement labels or labeling may, subject to the requirements in paragraphs (a) through (e) of this section, bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims under paragraph (g) of this section. If the label or labeling of a product marketed as a dietary supplement bears a disease claim as defined in paragraph (g) of this section, the product will be subject to regulation as a drug unless the claim is an authorized health claim for which the product qualifies.

(g) *Disease claims.* (1) For purposes of 21 U.S.C. 343(r)(6), a “disease” is damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.

¹²¹Id.

(2) FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease (other than a classical nutrient deficiency disease) under 21 U.S.C. 343(r)(6) if it meets one or more of the criteria listed below. These criteria are not intended to classify as disease claims statements that refer to the ability of a product to maintain healthy structure or function, unless the statement implies disease prevention or treatment. In determining whether a statement is a disease claim under these criteria, FDA will consider the context in which the claim is presented. A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product:

- (i) has an effect on a specific disease or class of diseases
- (ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;
- (iii) Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;
- (iv) Has an effect on a disease or diseases through one or more of the following factors:
 - (A) The name of the product;
 - (B) A statement about the formulation of the product, including a claim that the product contains an ingredient (other than an ingredient that is an article included in the definition of dietary supplement under 21 U.S.C. 321(ff)(3) that has been regulated by FDA as a drug and is well known to consumers for its use or claimed use in preventing or treating a disease;
 - (C) Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims;
 - (D) Use of the term disease or diseased, except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to a specific product or ingredient; or
 - (E) Use of pictures, vignettes, symbols, or other means;
- (v) Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;
- (vi) Is a substitute for a product that is a therapy for a disease;
- (vii) Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases;
- (viii) Has a role in the body's response to a disease or to a vector of disease;
- (ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or
- (x) Otherwise suggests an effect on a disease or diseases.

Dated October 26, 1999¹²²

The final rule was, of course, accompanied by a discussion of the implementation plan, the environmental impact and an analysis of impact. The analysis impact included a cost/benefit analysis, costs of compli-

ance (for labeling redesign and administrative costs, inventory losses, a total direct compliance costs and a sensitivity analysis).¹²³ For our purposes, no further discussion of these issues is required.

Reactions to the Final Rule

The final rule is interpreted (and criticized) in the following manner:

The critical distinction in the regulation between a structure/function claim and a drug claims centers on the *definition of the term “disease”*.... FDA also sets forth various criteria by which the agency will judge whether or not a given claim is a disease (and thus a drug) claim. In the preamble to the final regulation, FDA illustrates by example, particular disease claims (and acceptable structure/function claims) under these criteria. These criteria and the examples are somewhat helpful, but they still leave a substantial gray area. The line between many structure/function and disease claims will be subjective, and much will depend on wording, context, and interpretation. Also, the preamble is not the regulation, and the FDA is free to change its mind about particular examples without amending the regulation.

Furthermore, FDA states that the list of criteria is not exhaustive, and some examples given for acceptable structure/function claims are claims currently permitted for OTC drugs. This further blurs the boundary between drug and dietary supplement regulatory categories.¹²⁴

This commentator also identifies the test for identifying what is considered a sign or symptom characteristic of disease: “The test is whether signs or symptoms characteristic of a disease are mentioned in the claim. Not every sign or symptom need be mentioned.”¹²⁵ As to the subject of natural conditions, “[t]he key factors distinguishing a natural state from a disease are a) the severity of the condition, and b) the commonness of the condition.”¹²⁶

Criticism of the final rule focuses primarily on the ambiguities left undressed: “While FDA has made a good faith attempt to distinguish between structure/function claims and drug claims, certain claims that are acceptable structure/function claims are quite close in language and meaning to claims that are deemed

¹²³*Id.* at 1044-1047.

¹²⁵*Id.* at IV-4

¹²⁶*Id.*

disease (drug) claims.... Secondly, in a surprising move, FDA has indicated that there are acceptable structure/function claims that are identical or similar to drug claims in OTC monographs.”¹²⁷ Others claim that the final rule leaves unanswered questions: “Does [the rule] apply to oral representations?... Is it enough to notify the FDA once as opposed to notification for every product for which a particular claim was made?”¹²⁸ Another question which is not addressed is the long-term effects of the use of dietary supplements.¹²⁹

Suggestions

Both before and after the promulgation of the rule, many critics have offered suggestions for ameliorating the negative effects of the DSHEA itself and the FDA’s final rule. One critic suggested that the FDA should consider the impact of under-reporting of the adverse effects of specific dietary supplements and should require the inclusion of a hotline number on dietary supplement labels in order to promote accurate, timely reporting of adverse effects.¹³⁰ This critic also suggested that the “FDA should use its statutory publicity powers to challenge the marketing of vitamins with misleading health claims.”¹³¹

Another commentator has suggested that the FDA establish a regulatory scheme which mirrors its regulation of the cosmetic industry: “The FDA should encourage the dietary supplement industry to establish voluntary industry review programs similar to those of the cosmetic industry.... Voluntary reporting programs such as those found in the cosmetic industry are effective because industries prefer working with, rather than against, the government.”¹³² It should be noted, however, that the author of this suggestion recognized that

¹²⁷*Id. at IV-5.*

¹²⁸Bass & Young, *supra* note 14, at 58.

¹²⁹Kaczka, *supra* note 4, at 491-492.

¹³⁰O’Reilly, *supra* note 71, at 25.

¹³¹*Id.*

¹³²Lauren J. Sloane, “Herbal Garden of Good and Evil: The Ongoing struggles of Dietary Supplement Regulation, 51 Admin. L. Rev. 323, 340 (Winter, 1999).

cosmetics are a low-risk product, so the applicability of a similar regulatory scheme is questionable.

Others critics are concerned about inadequate and misleading labels have said that “[o]ne option to remedy this dilemma might be to utilize and insert or extended pull-out label that provides more complete information for the consumer to use in making an educated decision.”¹³³

Still another commentator suggests an altogether different test than has been established by the final rule: “The key concept determining whether a claims is permitted under § 403(r)(6) is not whether the claim is somehow related to one disease or another, but whether the claim when viewed in its entirety, is reasonably related to the promotion of overall good health and well-being.”¹³⁴

Another suggestion would place further limits on dietary supplement manufacturers:

Supplement manufacturers should have a legally enforceable affirmative obligation to do the testing needed to establish that supplements are safe. If they do not do safety testing, the manufacturer should put a warning on the label that the safety of the supplement has not been substantiated. Such a measurement would not require pre-market approval by FDA.¹³⁵

Such a suggesting tracks very closely with the court’s decision in *Pearson v. Shalala*, which can be expected to bear directly on any future litigation involving the final rule, as discussed below.

Pearson. Shalala

Although the courts have not addressed the viability of the FDA’s new rule, one might expect the courts to apply a similar reasoning to the new rule that the Court of Appeals for the District of Columbia did in *Pearson*

¹³³Carl Germano, “Structure/Function Claims – Do they Truly Benefit the Consumer? Despite the Legislative Strides made by DSHEA, the Battle Goes On. http://www.solgar.com/nutrient_library/opinion/structure_function.html.

¹³⁴Harrison, *supra* at note 13.

v. Shalala, 164 F.3d 650, 334 U.S.App.D.C. 71 (1999) (despite the FDA’s attempt to distinguish the case, as noted earlier). The case involved an objection, on constitutional grounds, to the FDA’s regulation under the NLEA of dietary supplement labeling because it did not consider allowing the inclusion of disclaimers which indicated the lack of both supporting studies and FDA approval but disallowed those claims altogether. Prior to the Court of Appeal’s decision in *Pearson*, “for health claims to be used, there need[ed] to be sufficient scientific agreement among qualified experts that the claim [were] factual and truthful.”¹³⁶ In *Pearson*, the FDA had rejected claims which did not meet its significant scientific agreement standard and rejected the suggested disclaimer. The appellants objected to the regulation in 21 C.F.R. § 101.14 on First Amendment grounds and claimed that the FDA was required under the Administrative Procedure Act to articulate its “significant scientific agreement” standard. The appellants further stated that even if the standard was spelled out, then should be allowed to make non-conforming health claims if they are accompanied with a disclaimer.

The Court of Appeals employed the *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*, 447 U.S. 557, 10 S.Ct. 2343, test, which considers three prongs: “First we ask whether the asserted government interest is substantial.... [Second,] ‘whether the regulation directly advances the governmental interest asserted.’... [Third,] whether the fit between the government’s ends and the meaning chosen to accomplish those ends ‘is not necessary perfect, but reasonable.’”¹³⁷ The court quickly identified the first prong as satisfied because the FDA has a significant interest in protecting the public interest by “ensuring the accuracy of commercial information in the marketplace.”¹³⁸

However, the court cites difficulties with the final two prongs of the test. The court views the FDA’s justification for the regulation as dubious, seeing it as rather paternalistic.¹³⁹ The court recognizes that the

¹³⁶Paula Kurtzweil, “Staking a Claim to Good Health: Health Claims on Foods.” FDA Consumer, p.16-18 (Nov./Dec. 1998).

¹³⁷*Pearson v. Shalala*, 164, F.3d 650, 656, 334 U.S.App.D.C. 71, 76-77 (citing *Central Hudson* 447 U.S. 557, 100 S.Ct. 2343).

¹³⁸*Id.* at 76.

¹³⁹*Id.*

second prong may, however, have been satisfied under a consumer fraud claim (although not applicable in the specific products involved). But, it is this consumer fraud claim which created a worry about satisfying the third prong of the *Central Hudson* test.¹⁴⁰ The FDA claimed that “it is never obliged to utilize the disclaimer approach because the commercial speech doctrine does not embody a preference for disclosure over outright suppression.”¹⁴¹ The court responds that “the preferred remedy is more disclosure, rather than less”¹⁴² under the First Amendment. The court flatly rejects “the government’s position that there is no general First Amendment preference for disclosure over suppression.”¹⁴³

The court notes that its decision as to the third prong does not hold that inadequate claims should, therefore be remedied by disclaimers and does not speak to the validity of the regulation in question. The court finds that the FDA’s interest could be satisfied by allowing for disclaimers.¹⁴⁴ It notes that the FDA “must still meet its burden of justifying a restriction on speech.”¹⁴⁵ The court only seems to support an outright ban when the evidence supporting a claim is irresolute.¹⁴⁶

Beyond the *Central Hudson* test, the court considered the appellant’s “claim that the agency is obliged to give some content to the phrase ‘significant scientific agreement.’”¹⁴⁷ The appellants make this claim under both the First and Fifth Amendments. The court agrees that both the APA claim and the Fifth Amendment claim are valid. The court ultimately decides the unarticulated standard issue under the APA:

¹⁴⁰*Id.* at 77-78.

¹⁴¹*Id.* at 77.

¹⁴²*Id.* (citing *Bates v. State Bar of Arizona*, 443 U.S. 350, 97 S.Ct. 2691, 53 L.Ed.2d 810 (1977)).

¹⁴³*Id.* at 79.

¹⁴⁴*Id.* at 80.

¹⁴⁵*Id.*

¹⁴⁶*Id.* at 81.

¹⁴⁷*Id.*

[T]he APA requires the agency to explain why it rejects their proposed health claims – to do so adequately necessarily implies giving some definitional content to the phrase ‘significant scientific agreement’. We think this proposition is squarely rooted in the prohibition under the APA that an agency not engage in arbitrary and capricious action.¹⁴⁸

The court concludes that “it must be possible for the regulated class to perceive the principles which are guiding agency action.”¹⁴⁹ The court requires, on remand, that the FDA provide an explanation and standards for meeting its “significant scientific agreement” standard.

It is hardly a stretch to recognize that the court’s decision in *Pearson* has far-reaching implications for the FDA’s regulatory process: “[T]his proposed reg, contradicts in its breadth some of the recent first amendment decisions from the D.C. Circuit. Including the Washington Legal Foundation [a plaintiff] of *Pearson v. Shalala*.”¹⁵⁰

A participant in the Committee on Government Reform hearing on March 25, 1999 summarized the holding of *Pearson* in the following manner:

A recent case in the U.S. Court of Appeals for the DC Circuit addressed the health claims issues. In this case, it was found that the FDA violated the first amendment by refusing to use disclaimers and authorize health claims. The FDA also violated the first amendment by prohibiting specific health claims. Additionally, the Court ruled that the FDA violated the Administrative Procedure Act by refusing to define its health claims review standard for dietary supplements.¹⁵¹

Another Representative described the FDA’s action in the following fashion:

... [T]he FDA has ruled that it is *illegal* for companies who market psyllium to speak about the benefits of this nutrient. *Illegal to speak*. The FDA took it upon itself to alter this little bit of the Constitution without bothering to check with the rest of us on it.¹⁵²

Despite the Court’s holding in *Pearson*, there exists the possibility the courts will follow the holding in *Henley v. FDA*, 873 F.Supp. 776 (DATES?) which that the FDA’s decision to deny a citizen’s petition for additional warning labeling on products containing estrogen was not arbitrary, capricious or an abuse of

¹⁴⁹Id. at 82.

¹⁵⁰Id. at 84.

discretion. The court found a rational basis for the denial and said that the decision was within the agency's authority.

In response to the court's decision in *Pearson*, the FDA ultimately published a final rule under the NLEA entitled "Food Labeling: Statement of Identity, Nutrition Labeling of Dietary Supplements: Compliance Policy Guide, Revocation " 21 C.F.R. § 101.36 (1998), 62 Fed.Reg. 49,826 (Sept. 23, 1997). This rule was intended to respond to the *Pearson* holding by providing more complete information on the labels of dietary supplements. The FDA may ultimately be forced to similar actions under the DSHEA.

Conclusion

With the implementation of its final rule concerning structure/function statements on dietary supplement labels, the FDA has attempted to implement the Dietary Supplement Health and Education Act. Whether it has succeeded remains to be seen. Although the FDA attempts to clarify the DSHEA with its recent promulgation of rules, the questions which remain to be addressed are varied and significant. Will the courts continue in their current direction in limiting restrictions on the marketing of dietary supplements? See *Pharmanex, Inc. v. Shalala*, 35 F.Supp.2d 1341 (D.Utah 1999). Will the FDA provide further guidance to manufacturers (and ultimately consumers) regarding acceptable structure/function claims? For surely, confusion exists as to acceptable claims as can be seen in the following statement in a recent news report: "[A product] can bear label advertising the product's ability to lower cholesterol."¹⁵³ This would certainly not be an acceptable structure/function, but the consumer would not know of the inaccuracy of this report.

Will scarce funding thwart the FDA's enforcement efforts in regulation the labeling of dietary supplement?¹⁵⁴

¹⁵³Daryn Eller, "Herbal Food Additives: Making Sense of the Claims," <http://www.cnn.com/HEALTH/9903/23/dietary.supplements/hs~index.html>, 9/20/00.

¹⁵⁴U.S. Says Lack of Funding Hampers Supplement Law. <http://www.cnn.com/2001/HEALTH/diet.fitness/03/21/health.supplements.reut/index.htm>. 3/21/01

Regardless of the answers to these pressing questions, it is clear that the increasing popularity of dietary supplements requires at least some level of regulation. Whether this regulation will be of the strict sort supported by the FDA or a lesser standard as intended by Congress remains to be seen.